DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

IMMUNODIAGNOSTIC SYSTEMS LTD.
ROMA YOUNG, REGULATORY AFFAIRS OFFICER
10 DIDCOT WAY, BOLDEN BUSINESS PARK
BOLDON, TYNE & WEAR, NE35 9PD
UNITED KINGDOM

March 30, 2015

Re: K143324
Trade/Device Name: IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: I, Reserved
Product Code: JJX
Dated: January 29, 2015
Received: February 6, 2015

Dear Roma Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Katherine Serrano -S

For: Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k143324

Device Name
IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers

Indications for Use *(Describe)*
The IDS-iSYS CTX-l (CrossLaps ®) Calibration Verifiers is a device intended for the verification of calibration of the IDS-iSYS CTX-I (CrossLaps ®) Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

k143324

510(k) SUMMARY

Introduction According to the requirements of 21CFR807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

Submitter Immunodiagnostic Systems Ltd
10 Didcot Way
Boldon Business Park
Boldon
Tyne and Wear
NE35 9PD
United Kingdom

Contact Person: Roma Young
Phone: +44 191 5190660
Fax: +44 191 5190760
Email: roma.young@idsplc.com

Secondary Contact: Mick Fenton
Phone: +44 191 5190660
Fax: +44 191 5190760
Email: michael.fenton@idsplc.com

Date Prepared: March 23rd, 2015

Device Name:

Proprietary names:	IDS-iSYS CTX-I (Crosslaps®) Calibration Verifiers
Common names:	As above
Classification:	21CFR862.1660 (Class I, Reserved)
Product Code:	JJX

Device Description: The IDS-iSYS CTX-I (CrossLaps®) Calibration Verifiers consists of one set of four vials, 2.5 mL each in liquid form, containing horse serum with <0.1% (w/w) sodium azide as a preservative, with four concentration levels of human CTX-I:

Cal. Ver. 0: Undetectable
Cal. Ver. 1: 0.12 - 0.16 ng/mL
Cal. Ver. 2: 2.4 - 3.2 ng/mL
Cal. Ver. 3: 5.6 - 6.6 ng/mL

Predicate Device: IDS-iSYS CTX-I (Crosslaps ®) Calibration Verifiers

Predicate 510(k): k111650

Special Conditions for Use: For in vitro diagnostic use; for prescription use.

Special instrument Requirements: IDS-iSYS Multi-Discipline Automated Analyzer

Intended Use: The IDS-iSYS CTX-l (CrossLaps®) Calibration Verifiers is a device intended for the verification of calibration of the IDS-iSYS CTX-I (CrossLaps®) Assay when performed on the IDS-iSYS Multi-Discipline Automated Analyzer.

Comparison with predicate:

Similarities	**Predicate Device**	**Candidate Device**
Indications for Use	The IDS-iSYS CTX-I CrossLaps®) Calibration Verifiers is a device intended for the verification of calibration of the IDS-iSYS CTX-I (CrossLaps ®) Assay when performed on the IDS-iSYS multi-disciplined automated analyzer.	Same
Analyte	CTX-I	Same
Values	Cal. Ver. 0: 0.0 ng/mL Cal. Ver. 1: 0.6 ng/mL Cal. Ver. 2: 3.0 ng/mL Cal. Ver. 3: 5.0 ng/mL	Cal. Ver. 0: Undetectable Cal. Ver. 1: 0.12 – 0.16 ng/mL Cal. Ver. 2: 2.4 – 3.2 ng/mL Cal. Ver. 3: 5.6 – 6.6 ng/mL
Levels	Levels 0, 1, 2, 3	Same
Analyzer System	IDS-iSYS Multi-Discipline Automated Analyzer	Same
Stability	2-8°C – unopened until expiration date On board stability: Single use-use then discard	2-8°C – unopened until expiration date On board stability: 3 hours, single use only.
Differences	**Predicate device**	**Candidate device**
Matrix	Liquid, phosphate bovine serum albumin	Horse serum containing CTX-I and sodium azide as preservative (<0.1%). 1 vial each of levels 0-3 (2.5 mL).

Table 1

Performance Characteristics

Traceability and Value Assignment

The IDS-iSYS CTX-I assay is standardized against in-house reference standards (CTX-I in horse serum). Four levels of calibrator verifiers were used to validate the calibration on the IDS-iSYS and validate the range of the analytical measurement. Each lot-specific value assignment was tested in five runs on at least three different IDS-iSYS analyzers in triplicate, for a total of 45 replicates. The assigned target value of each calibrator verifier was defined as the mean of all the runs for each calibrator verifier. The guideline target range is defined as the mean of all runs ± 2SD.

The following target mean values and ranges for each calibrator verifier provided in Table 2 are typical for the product and are intended as a guide only. Values may vary from lot to lot.

CVM	Target Mean (ng/mL)	Standard Deviation (SD)	Target Range (ng/mL)
Cal. Ver. 0	0 (Undetectable)	NA	NA
Cal. Ver. 1	0.14	0.009	0.12 – 0.16
Cal. Ver. 2	2.8	0.168	2.4 – 3.2
Cal. Ver. 3	6.1	0.366	5.6 – 6.6

Table 2

Stability

On board stability studies in accordance with the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) were performed with kit calibrators and controls. 250µl of each were placed in 500µl cups. Five sets of calibration verifiers were placed on board. At each of five time points (T0=0, T1=1h, T2=2h, T3=3h and T4=4.5h) one set was tested. The concentrations of samples were interpolated from a validated 2point calibration. Data produced supports a claim of three hours on board stability.

Accelerated stability studies performed in accordance with the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) using two point calibration support a shelf life stability claim of twelve months.

All acceptance criteria were met.

Real time stability studies in accordance with the CLSI guideline EP25-A (Evaluation of stability of In Vitro Diagnostic Reagents) to support the above claims are ongoing.

Proposed Labeling

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

Conclusion

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.